

REMARKS

Claims 1-36 will be pending upon entry of the presently made amendments. Claims 3-21, 24, 25 and 36 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1 and 2 have been amended without prejudice to recite that the patient is experiencing pain. Support for these amendments is found in the specification as filed at least at page 20, line 32 to page 21, line 21.

Claim 31 has been amended without prejudice to remove the recitation of the phrase "another painful neuropathic condition."

No new matter has been added.

Applicants reserve their right to prosecute the subject matter of any canceled claim, any amended claim, any withdrawn claim or any unclaimed subject matter in one or more related applications.

I. The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 31 remains rejected under 35 U.S.C. § 112, second paragraph. In particular, the Examiner has stated that the term "pain" in claim 31 is used to mean "lost hair, dry hand, color change to the skin, weakness, edema, increased sweating... etc", while the accepted meaning is "pain, hyperalgesia, nociception, etc."

Applicants respectfully traverse this rejection and note that claim 31 was previously amended to recite that the pain can be "associated with" the recited conditions. In other words, the term "pain" as used in claim 31 does not mean "lost hair, dry hand, color change to the skin, weakness, edema, increased sweating... etc", but can mean pain associated with these conditions.

The Examiner has further stated that the phrase "another painful neuropathic condition" renders the claim vague. Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claim 31 to delete the phrase "another painful neuropathic condition."

Accordingly, Applicants submit that the rejection of claim 31 under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

II. The Rejection Under 35 U.S.C. § 102(e) over U.S. Patent No. 6,897,231 B2

Claims 1, 2 and 28-35 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,897,231 B2 to Bhagwat *et al.* (the "231 patent"). The

Examiner has stated that the '231 patent teaches that Applicants' active agent is useful for the treatment of stroke, asthma, osteoarthritis, rheumatoid arthritis, gout, burn from exposure to fire, chemical radiation, traumatic injury and lupus erythematosus, diabetes and cancers of a variety of tissues and, accordingly, discloses patients in need of treating pain as instantly claimed. The Examiner has further stated that the '231 patent inherently achieves all functional clinical effects because the same active agent is administered to the same subject population.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite that the patient is experiencing pain. Accordingly, Applicants respectfully submit that the '231 patent does not anticipate any of the pending claims at least because the patient population to be treated is different than that disclosed by the '231 patent.

In order to establish inherency, it must be clear that the missing descriptive matter is necessarily present in the reference and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); M.P.E.P. § 2112. In other words, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

As Applicants have previously noted and as taught by the literature, it is well established that pain is separate and distinct from disease, wherein the treatment of a particular disease does not necessarily treat pain. *See Woolf and Decosterd, 1999, "Implications of recent advances in the understanding of pain pathophysiology for the assessment of pain in patients," Pain Supplement 6:S141-S147* (previously submitted as reference C01). Thus, patients having a disease taught by the '231 patent might not necessarily experience pain associated with the disease and, conversely, patients could experience pain after a disease taught by the '231 patent has been treated or managed.

By way of example, a patient can have cancer without experiencing pain or could experience pain after a cancer is in remission. Another illustrative example is phantom limb pain. Specifically, it is well documented that many amputees experience the persistence of severe pain in their missing limb. *See first sentence at page 57 of N. Postone, 1987, "Phantom Limb Pain. A Review," Int'l. Psychiatry in Medicine 17(1):57-70* (previously submitted as reference C03). In fact, such pain may arise even up to 15 years after amputation (*i.e.*, long after any injury has healed). *Id.* at last full sentence at page 59. Accordingly, at least because the patient population taught by the '231 patent differs from

that of the presently pending claims, Applicants respectfully submit that the '231 patent does not inherently anticipate any of the pending claims.

Claims 28-35 depend directly or indirectly from claim 1.

Accordingly, Applicants submit that the rejection of claims 1, 2 and 28-35 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

III. The Rejection Under 35 U.S.C. § 102(e) over U.S. Patent No. 6,897,231 B2 Evidenced by U.S. Patent No. 5,766,605 or U.S. Patent No. 5,434,136

Claims 1, 2 and 28-31 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by the '231 patent evidenced by U.S. Patent No. 5,766,605 A to Sanders *et al.* (the "'605 patent") or U.S. Patent No. 5,434,136 A to Mathias (the "'136 patent"). In particular, the Examiner has stated that the '231 patent teaches the active agent of the pending claims for the treatment and prevention of lupus erythematosus and asthma, the '605 patent teaches that asthma is autonomic dysfunction, and the '136 patent teaches that lupus erythematosus is autonomic dysfunction. The Examiner has further stated that the subject population ("a patient in need thereof") to be treated is the same and, thus, the '231 patent evidenced by the '605 patent or the '136 patent inherently anticipates the pending claims.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite that the patient is experiencing pain. Claims 28-31 depend directly or indirectly from claim 1.

Applicants submit that the pending method for treatment claims are not anticipated by the '231 patent evidenced by the '605 patent or the '136 patent for the same reasons as set forth above.

Accordingly, Applicants submit that the rejection of claims 1, 2 and 28-31 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

IV. The Rejection Under 35 U.S.C. § 102(e) over U.S. Patent Application Publication No. 2004/0067953 A1

Claims 1, 2 and 28-31 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2004/0067953 A1 to Stein *et al.* (the "'953 publication"). In particular, the Examiner has stated that the '953 publication teaches the treatment of cancer by the administration of an effective amount of Applicants' active agent and, therefore, patients disclosed by the '953 publication are "in need of" treatment for pain since it is allegedly well known in the art that pain is associated with cancer.

Applicants respectfully disagree and submit that as discussed above, it is quite possible for a patient to have cancer without experiencing pain. Applicants respectfully submit that, for example, a cancerous tumor can begin to grow in patient without the patient feeling any pain or discomfort at all. Furthermore, pain which is triggered by a tumor can linger after the tumor is removed.

Nevertheless, without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite that the patient is experiencing pain. Claims 28-31 depend directly or indirectly from claim 1.

Applicants submit that the pending method for treatment claims are not anticipated by the '953 publication for the same reasons as set forth above.

Accordingly, Applicants submit that the rejection of claims 1 and 28-31 under 35 U.S.C. § 102(e) has been overcome and should be withdrawn.

V. The Rejection Under 35 U.S.C. § 103(a) over U.S. Patent No. 6,897,231 B2

Claims 22, 23, 26 and 27 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,897,231 B2 to Bhagwat *et al.* (the "'231 patent"). In particular, the Examiner has stated that the '231 patent teaches that the compounds can be administered together with another biologically active agent and that the compounds can be formulated with a local anesthetic such as lignocaine to ease pain at the site of the injection. The Examiner has acknowledged that the '231 patent does not teach the specific agents set forth in claim 27.

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicants have amended claims 1 and 2 to recite that the patient is experiencing pain. Claims 22, 23, 26 and 27 depend directly or indirectly from claim 1 or claim 2.

Although, the '231 patent teaches that other active agents can be used in combination with a JNK inhibitor, Applicants respectfully submit that it does not teach the use of a JNK inhibitor for the treatment of pain and that no reason has been provided as to why one of ordinary skill in the art would modify the teaching of the '231 patent in order to arrive at such use. ([T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) cited with approval in *KSR International Co. v. Teleflex Inc.* 127 S.Ct. 1727 (2007)). Notably, although a rigid application of the teaching, suggestion, motivation test was rejected by the Supreme Court in *KSR*, the Federal Circuit has recently held that flexible teaching, suggestion, motivation test remains the primary guarantor against a non-statutory hindsight

analysis. *Ortho-McNeil Pharmaceuticals, Inc. v. Mylan Laboratories*, 520 F.3d 1358, 1364-1365 (Fed. Cir. 2008). In particular, the Federal Circuit explicitly stated that the identification of a reason why the ordinarily skilled artisan would make the selections needed to arrive at a claimed invention is still required. *Id.* One cannot simply retrace the path of the inventor with hindsight, discounting the number and complexity of the alternatives, and conclude that an invention is obvious. *Id.* In view of the above discussion, Applicants respectfully submit that a proper *prima facie* case of obviousness has not been established because a reason for making the modifications to the prior art necessary to arrive at the presently claimed invention has not been provided.

Applicants respectfully submit that although the '231 patent teaches the administration of lignocaine to ease pain at the injection site when a JNK inhibitor is administered intravenously, this does not suggest the use of a JNK inhibitor itself for the treatment of pain.

Accordingly, Applicants submit that the rejection of claims 22, 23, 26 and 27 under 35 U.S.C. § 103(a) has been overcome and should be withdrawn.

Conclusion

Applicants respectfully request that the above remarks be entered in the present application file. No fee is estimated to be due in connection with this Response; however, in the event that any fee is due, please charge the required fee to Jones Day Deposit Account No. 50-3013.

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Respectfully submitted,
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